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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

24265 7590 08/09/2007
SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/21/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,17-23 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, 17-23, and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to the claims, filed on May 21, 2007, has been entered.

Claims 1-6, 8, 10-16, 24, and 30 have been canceled.

Claim 7 has been amended.

Claims 7, 9, 17-23, and 25-29 are pending and currently under consideration as they read on the originally elected invention of a purified antibody or fragment thereof specifically binds to an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO:6.

2. This Office Action is in response to Applicant's amendment to the claims, Remarks, and the Phillips declaration under 37 C.F.R. 1.132 filed on May 21, 2007.

3. The rejections of record can be found in the previous Office Actions, mailed on February 22, 2006, July 17, 2006 and November 20, 2006.

4. In light of applicant's amendment to the claims, the previous rejections under 35 U.S.C. 112, second paragraph have been withdrawn.

5. The prior rejection under 35 U.S.C. 102(b) has been withdrawn in view of applicant's amendment to the claims filed on May 21, 2007.

6. This is a **New Ground of Rejection.** The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7, 9, 17-23, and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The phrase "but does not bind the polypeptide consisting of the amino acid sequence of SEQ ID NO:2" recited in claims 7, 9, 17-23, and 25-29 are not supported by the original disclosure or claim as filed.

Applicant's Remarks in conjunction with the Phillips declaration under 37 C.F.R. 1.132, filed on May 21, 2007, have been fully considered but have not been found persuasive.

Applicant's amendment, filed on May 21, 2007, directs to support to pages 5-7, 18 and 21, and asserts that since the specification discloses structural and functional differences between FDF03 (SEQ ID NO:2) and FDF03-S1 (SEQ ID NO:6), one skilled in the art would know that applicant contemplated the generation of antibodies that bind SEQ ID NO:6 but do not bind SEQ ID NO:2.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitations". The specification does not provide sufficient support for a purified antibody or fragment thereof which specifically binds SEQ ID NO:6 but does not bind the polypeptide consisting of SEQ ID NO:2. The specification only discloses antibody that binds SEQ ID NO:6; the instant claims now recite a purified antibody or fragment thereof which specifically binds SEQ ID NO:6 but does not bind the polypeptide consisting of SEQ ID NO:2, which were not clearly disclosed in the instant specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on the generic disclosure of the structural and functional differences between SEQ ID NOs: 2 and 6 and the uses of the antibodies do not provide sufficient direction and guidance to the features currently claimed. It is noted that a generic or a sbu-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

The specification does not have sufficient support for "but does not bind the polypeptide consisting of the amino acid sequence of SEQ ID NO:2". The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

8. This is a **New Ground of Rejection**. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 7, 9, 17, 18, 20-23, and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. (US Patent Application 2005/0155089).

Lal et al. teach human signal peptide containing proteins including proteins with amino acid sequence of SEQ ID NO:7 that is 100% identical to the instant SEQ ID NO:6 (see paragraph [0041] and attached sequence alignment, in particular).

Lal et al. further teach purified antibodies that bind human signal peptide containing protein of SEQ ID NO:7 including monoclonal antibodies, antibody fragments such as Fab, Fv, recombinant antibody, e.g. humanized antibody or fragment thereof, and hybridoma that produces antibodies (see entire document, particular paragraphs [0074] and [0144]-[0153]). Furthermore, Lal et al. teach a pharmaceutical composition, comprising said antibodies and pharmaceutically acceptable carriers, suitable for parenteral administration including subcutaneous or intravenous administration (e.g. see paragraphs [0168]-[0183]).

Given that the referenced SEQ ID NO:7 is 100% identical to the instant SEQ ID NO:6, the reference antibody would inherently bind the instant SEQ ID NO;6 but would not bind the instant SEQ ID NO:2.

Therefore, the reference teachings anticipate the claimed invention.

10. This is a **New Ground of Rejection**. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lal et al. (US Patent Application 2005/0155089) in view of Markussen (US Patent 5,317,092).

The teachings of Lal et al. have been discussed, supra, and teach that antibody binds human signal peptide containing protein with amino acid sequence of SEQ ID NO:7 can be used in various immunoassays such as ELISA (e.g. see paragraph [0154] and [0186]).

The reference teachings differ from the claimed invention by not describing an antibody or fragment thereof that is bound to a solid support.

Markussen teaches that antibodies immobilized to a solid support provide convenience for a method for isolating their target proteins or polypeptides in substantially pure form (see entire document, particularly column 2).

Therefore, it would have been obvious to the ordinary artisan at the time the invention was made to immobilize the antibody to a solid support.

The ordinary artisan would have been motivated to do so because antibodies immobilized to a solid support can be used in a convenient method for isolating their target proteins or polypeptides in substantially pure form.

Given the teachings of Lal et al. providing the uses of antibody in various immunoassys and the teachings of Markussen regarding method of using antibody immobilized to a solid support, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success of producing the claimed antibody or fragment thereof that is bound to a solid support.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Conclusion: no claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Crowder
Patent Examiner
August 2, 2007
Attachment: amino acid sequence alignment

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER

<!--StartFragment-->RESULT 5
US-10-820-474A-7
; Sequence 7, Application US/10820474A
; GENERAL INFORMATION:
; APPLICANT: LAL, PREETI
; APPLICANT: TANG, Y. TOM
; APPLICANT: GORGONE, GINA A.
; APPLICANT: CORLEY, NEIL C.
; APPLICANT: GUEGLER, KARL J.
; APPLICANT: BAUGHN, MARIAH R.
; APPLICANT: AKERBLOM, INGRID E.
; APPLICANT: AU-YOUNG, JANICE
; APPLICANT: YUE, HENRY
; APPLICANT: PATTERSON, CHANDRA
; APPLICANT: REDDY, ROOPA
; APPLICANT: HILLMAN, JENNIFER L.
; APPLICANT: BANDMAN, OLGA
; TITLE OF INVENTION: SIGNAL PEPTIDE-CONTAINING MOLECULES
; FILE REFERENCE: 039386-1568
; CURRENT APPLICATION NUMBER: US/10/820,474A
; CURRENT FILING DATE: 2004-04-07
; PRIOR APPLICATION NUMBER: 09/720,533
; PRIOR FILING DATE: 2001-03-20
; PRIOR APPLICATION NUMBER: PCT/US99/14484
; PRIOR FILING DATE: 1999-06-25
; PRIOR APPLICATION NUMBER: 60/090,762 ← SEQ ID NO 7
; PRIOR FILING DATE: 1998-06-26
; PRIOR APPLICATION NUMBER: 60/094,983
; PRIOR FILING DATE: 1998-07-31
; PRIOR APPLICATION NUMBER: 60/102,686
; PRIOR FILING DATE: 1998-10-01
; NUMBER OF SEQ ID NOS: 269
; SOFTWARE: PatentIn version 3.3
; SEQ ID NO 7
; LENGTH: 227
; TYPE: PRT
; ORGANISM: Homo sapiens
; FEATURE:
; NAME/KEY: misc_feature
; OTHER INFORMATION: Incyte Clone No: 962390
US-10-820-474A-7

Query Match 100.0%; Score 1192; DB 38; Length 227;
Best Local Similarity 100.0%; Pred. No. 7.3e-108;
Matches 227; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 MGRPLLLPLLLLLQPPAFLQPGGSTGSGPSYLYGVTQPKHLSASMGGSVEIPFSFYYPWE 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MGRPLLLPLLLLLQPPAFLQPGGSTGSGPSYLYGVTQPKHLSASMGGSVEIPFSFYYPWE 60

Qy         61 LAIVPNVRISWRRGHFHGQSFYSTRPPSIHKDYVNRLFLNWTEGQESGFLRISNLRKEDQ 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 LAIVPNVRISWRRGHFHGQSFYSTRPPSIHKDYVNRLFLNWTEGQESGFLRISNLRKEDQ 120

Qy        121 SVYFCRVELDTRRSGRQQLQSIKGTKLTITQAVTTTTTWRPSSTTTIAGLRVTESKGHSE 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SVYFCRVELDTRRSGRQQLQSIKGTKLTITQAVTTTTTWRPSSTTTIAGLRVTESKGHSE 180

Qy        181 SWHLSLDTAIRVALAVAVLKTVILGLLCLLLLWWRRRKGSRAPSSDF 227
              |||||||||||||||||||||||||||||||||||||||||||||||
Db        181 SWHLSLDTAIRVALAVAVLKTVILGLLCLLLLWWRRRKGSRAPSSDF 227
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